(b) *Special considerations.* Do not use in Type B or Type C medicated feed containing bentonite.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) *Conditions of use.* It is used in feed for animals as follows:

(1) *Cattle*—(i) *Amount.* 3 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*).

(*b*) *Limitations.* Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp.*

(*b*) *Limitations.* 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Goats*—(i) *Amount.* 3 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).

(iii) *Limitations.* 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) *Sheep and goats*—(i) *Amount.* 2 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp.; Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.;* less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations.* Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) *For swine*—(i) *Amount.* 45.4–908 grams per ton (0.005–0.1 percent).

(ii) *Indications for use.* Aid in the prevention of infections of large roundworms (genus *Ascaris*).

(iii) *Limitations.* Administer continuously feed containing 0.05–0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005–0.02 percent thiabendazole per ton for 8–14 weeks; do not treat animals within 30 days of slaughter.

(5) *Pheasants*—(i) *Amount.* 454 grams per ton (0.05 percent) continuously for 2 weeks (14 days).

(ii) *Indications for use.* For the treatment of gapeworms *(Syngamus trachea)* in pheasants.

(iii) *Limitations.* Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals.

[40 FR 13959, Mar. 27, 1975, as amended at 47 FR 49641, Nov. 2, 1982; 49 FR 29958, July 25, 1984; 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 62 FR 63271, Nov. 28, 1997]

§ 558.618 Tilmicosin.

(a) *Specifications.* Type A medicated article containing 20 percent tilmicosin as tilmicosin phosphate (90.7 grams per pound).

(b) *Approvals. See* No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) Federal law limits this drug to use under the professional supervision of a licensed veterinarian. *See* § 558.6 of this chapter for additional requirements for the use of products regulated as veterinary feed directives (VFDs).

(2) The expiration date of VFDs for tilmicosin must not exceed 90 days from the time of issuance. VFDs for tilmicosin shall not be refilled.

(3) Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances.* See § 556.735 of this chapter.

(e) *Conditions of use.* It is used in swine feed as follows:

(1) *Amount per ton.* 181 grams to 363 grams tilmicosin.

(2) *Indications for use.* For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida.*

(3) *Limitations.* Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an expected disease outbreak. Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before reinitiating a further course of therapy with an appropriate antimicrobial. The safety of tilmicosin has not been established in male swine intended for breeding purposes. Do not allow horses or other equines access to feeds containing tilmicosin. Withdraw 7 days before slaughter.

[61 FR 68148, Dec. 27, 1996; 62 FR 15391, Apr. 1, 1997, as amended at 64 FR 13679, Mar. 22, 1999; 65 FR 76930, Dec. 8, 2000; 67 FR 21997, May 2, 2002; 69 FR 78306, Dec. 30, 2004]

§ 558.625 Tylosin.

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means. Tylosin, present as the phosphate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled ''Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,'' which is incorporated by reference. Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) *Approvals.* Type A medicated article levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

(1) To 000986: 10, 40, 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(2) [Reserved]

(3) To 043733: 20 and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(4) [Reserved]

(5) To 017800: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(6)–(7) [Reserved]

(8) To 035369: 4 and 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 10 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(9) [Reserved]

(10) To 017519: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (f)(1)(vi) of this section.

(11) [Reserved]

(12) To 021930: 2 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(13) [Reserved]

(14) To 016968: 1, 2, 4, 8, and 10 grams per pound, paragraphs (f)(1) (i), (iii), (iv), and (vi) of this section; 20, 25, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(15)–(21) [Reserved]